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	Application Number		10530794	
	Filing Date		2005-04-08	
INFORMATION DISCLOSURE	First Named Inventor Francis Thor		as Thomas Boyle	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1614	
(NOCION SUDMISSION UNION ST OF R 1.33)	Examiner Name	James D. Anderson		
	Attorney Docket Numb	er	100864-1P US	

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Examiner Cite Initial* No Patent No		Patent Number	Kind Code ¹	Issue D)ate	Name of Pat of cited Docu	entee or Applicant ument	Relev	s,Columns ant Passa es Appear	iges or F	
	1	5770599		1998-06	i-23	Gibson					
	2	5457105		1995-10	I- 1 0	Barker					
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	2	1424080	EP	A1	2004-06-02	Takeda Chemical Industries			
	3	0823900	EP	B1	1998-02-18	AstraZeneca AB			
	4	0566226	EP	B1	1995-11-08	Zeneca Limited			
	5	2003/072108	wo	A1	2003-09-04	AstraZeneca AB			
	6	2001/76586	wo	A1	2001-10-18	AstraZeneca AB			
	7	2003/088971	wo	A1	2003-10-30	AstraZeneca AB			
	8	2004/014426	wo	A1	2004-02-19	AstraZeneca AB			
	9	2005/004872	wo	A1	2005-01-20	AstraZeneca AB			
	10	2005/117888	wo	A1	2005-12-15	AstraZeneca AB			
	11	2005/063735	wo	A1	2005-07-14	Merck Patent GMBH		×	
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Examiner Initials*	Cite No	Include name of the author (in CAPTIAL LETTENS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MORRIS MICHAEL JET AL: "Clinical approaches to osseous metastases in proclate cancer." The Oncologist, 2003, pages 161-173, vol. 8, no. 2	
	2	ROSANO LAURA A ET AL: "Therapeutic targeting of the endohelin a receptor in human ovarian cardinoma," Cancer Research, 15 May 2003 (2003-05-15), pages 2447-2453, vol. 63, no. 10, XP002365689	
	3	WALCZAK J R ET AL: "Pharmacological Treatments for Prostate Cancer," Expert Opinion on Investigational Drugs, 2002, pages 1737-1748, Vol. 11, no. 12, Ashley Publications, Ltd., London, GB, XP009008862	
	4	ROSANO, LAURA ET AL, "ZD4054, a specific antagonist of the endothelin A receptor, inhibitis tumor growth and enhances cytotoxicity of pacitiaxel in human ovarian carcinoma in vitro and in vivo," April 16-20, 2005, AACR, Anahelmi/Crange County, CA	
	5	CURTIS, N. ET AL: "ZD4054 specifically inhibits endothelin A receptor-mediated anti-apoptotic effects, but not endothelin B receptor-mediated pro-apoptotic effects," September 28-October 1, 2004, AACR-NCI-EORTC, Geneve, Switzerland	
	6	LIU, GLENN ET AL, "Tolerability profile of ZD4054 is consistent with the effects of endothelin A receptor-specific antagonism," May 13-17, 2005, ASCO Annual Meeting, Orlando, Flonda	
	7	MORRIS, C. ET AL, "ZD4054: specificity for endothelin A receptor following single-dose administration in healthy volunteers," September 28-October 1, 2004, AACR-NCH-EORTC, Geneva, Switzerland	
	8	DREICER, R. ET AL., "ZD4054 specifically inhibits endothelin A receptor-mediated effects but not endothelin B receptor-mediated effects," February 17-19, 2005, ASCO Prostate Cancer Symposium, Orlando, Florida	
	9	TODD, MARTIN ET AL, "Metabolite Faconies: Use of microbial systems to generate metabolites of an endothelin receptor antagonisa," July 3-8, 2005, Biotrans 2005, Dellt, The Netherlands	
	10	MORRIS, CD ET AL. "Specific inhibition of the endothelin A receptor with ZD4054: clinical and preclinical evidence," British Journal of Cancer, 2005 92, 2148-2152	

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Date Considered

	11	CURTIS, N. ET AL, "ZD4054 blocks ET-1-stamulated phosphorylation of p4442 mtogen-activated protein kinase and proliferation of osteoblast cells," April 16-20, 2005, AACR, Anaheim/Drange County, CA						
	12	MIORRIS, C.D. ET AL, "ZID4054 reduces endotherin-1-induced forearm vasoconstriction in healthy male volunteers," April 16-20, 2005, AACR, Anshem/Crange County, CA						
	13	ROSANO, LAURA, "Combined targeting of the endothelin receptor and the epidermal growth factor receptor in ovarian cancer shows enhanced antiproliferative effects," April 1-5, 2006, AACR 2006, Washington, D.C.						
	14	CURWEN, J.O., "ZD4054": a specific endothetin A receptor antagonist with potential utility in prostate cancer and metasatic borne disease; European Journal of Cancer, November 2002 (2002-11), vol. 58., page \$102, Pergamon Peres, Diotor, 68, XP004463752.						
	15	NELSON, J.B., "The role of endothelin-1 and endothelin receptor antagonists in product cancer," British Journal of Urology, 2000, pages 45-46, 85, Suppl 2						
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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Sea 97 CFF 1.57(e)(1).

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- See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Lucy Padget/	Date (YYYY-MM-DD)	2007-01-08
Name/Print	Lucy Padget	Registration Number	L0074

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